REMARKS

Status of the Claims

Claims 1, 14-17, 19, 38, 55-60, 64, 66-71, 75 and 77 are in the application.

Claims 1, 14-17, 19, 55-60, 66-71 and 77 are rejected.

Claims 38, 64 and 75 have been withdrawn from consideration.

By way of this amendment, claims 38, 64 and 75 have been canceled as being directed to non-elected species. No new matter has been added.

Upon entry of this amendment, claims 1, 14-17, 19, 55-60, 66-71 and 77 will be pending.

Claim Rejection – 35 USC § 103

Yang et al. in view Letvin et al., Levinson et al. and Meazza et al.

Claims 1, 14, 16, 17, 19, 55, 56, 58-60, 66, 67, 69-71 and 77 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Yang et al. (Yang et al., Induction of potent Thl-type immune responses from a novel DNA vaccine for West Nile virus New York isolate (WNV-NY 1999). J *Infect Dis.* 184(7):809-16, 2001) in view Letvin et al. (WO 99/16466, international publication date 04/08/1999) and Levinson et al. (US 2006/0052592, publication date 03/09/2006, PCT/US03/19383 filed on 06/20/2003, provisional application No: 60/390,304 filed on 06/20/2002) and Meazza et al. (Meazza et al., Expression of two interleukin-15 mRNA isoforms in human tumors does not correlate with secretion: role of different signal peptides, *Eur J Immunol.* 27(5): 1049-54, 1997).

Yang discloses induction of Th1-type immune responses from a novel vaccine for WNV using recombinant DNA based vaccines that include coding sequences for WNV immunogenic targets linked to human immunoglobulin secretory sequences. Yang et al. does not explicitly teach (i) the limitation "from the same species as the non-IgE protein" recited in claims 1 and 55, and (ii) the limitation the immunomodulating protein is a cytokine recited in claim 1 and the limitation the non-IgE protein is an immunomodulating protein is IL-15 recited in claim 77, (iii) the limitation "IgE signal peptide" recited in claims 1, 55 and 66.

Letvin et al. (WO 99/16466) teaches a vaccine composition having a mammalian cytokine fusion protein (e. g., murine or human).

Levinson et al. teaches human IgE signal peptide in the construction and in vitro expression of human IgE tetanus fusion protein (See Figure 2, Levinson et al., US 2006/0052592, shown below, which is also disclosed in Figure 2 of provisional application No: 60/390,304 filed on 06/20/2002).

Meazza et al. teaches that Interleukin (IL)-15 is a four-helix bundle cytokine sharing several biological properties with IL-2.

It is asserted that it would have been *prima facie* obvious to one having ordinary skill in the art at the time of the invention to combine the teachings of Yang et al. regarding a recombinant DNA vaccine, a plasmid construct, as a pharmaceutical composition comprises a nucleic acid sequence encoding the human immunoglobulin secretory leader signal (See sIg leader, indicated in Figure 1A, Yang et al., 2001, and the plasmid map provided below) fused West Nile Virus (WNV) capsid protein (Cp), with the teachings of (i) Letvin et al. regarding the use of plasmid-expressed human cytokine IL-15 as a strategy for augmenting immune responses elicited by plasmid DNA vaccines, (ii) Levinson et al. regarding human IgE signal peptide in the construction and in vitro expression of human IgE tetanus fusion protein, and (iii) Meazza et al. regarding substitution of the sequence encoding natural human IL-15 signal peptide(s) with the signal peptide from IgVx chain in the IL-15 cDNA results in a significantly higher secretion of biologically active IL-15 upon cDNA transfection, to arrive at isolated nucleic acid recited in claims 1, 14, 16, 17,19, 55, 56, 58-60, 66, 67, 69-71 and 77 of instant application by substitution of WNVCp encoding sequences taught by Yang et al. with IL-15 coding sequence and fused to either sIg leader taught by Yang et al. or fused to human IgE signal peptide taught by Levinson et al. for expression of human IL-15 with desired secretion level taught by Meazza et al., in the context of the plasmid taught by either Yang et al. (2001) or Letvin et al. (1999).

Applicants respectfully request that the rejection be withdrawn as the disclosure in Levinson regarding the use of the IgE leader sequence is Applicants' invention and therefore, the cited teachings in Levinson used to establish the prima facie case are not available for such use.

The instant application is a national stage application of a PCT application filed June 14, 2004 which claims priority to two U.S. Provisional applications, each filed June 13, 2003.

The Levinson application, US 2006/0052592, which was published March 9, 2006 is a national stage application of PCT/US03/19383 filed on June 20, 2003 which itself claims priority to provisional application No: 60/390,304 filed on June 20, 2002.

Accordingly, the Levinson application was not published until after the effective filing date of the instantly claimed invention and only qualifies as prior art under 35 U.S.C. 102(e). as noted in the Official Action, Figure 2 in Levinson is disclosed in the provisional application filed June 20, 2002 to which Levinson claims priority.

Provided herewith is an unexecuted Declaration of co-inventor David B Weiner who is also a co-inventor in the cited Levinson et al. application. The Declaration of David B. Weiner states that co-inventors in Levinson did not conceive of or contribute to the conception of using IgE leader sequences in fusion proteins. The Declaration of David B. Weiner states that the conception of using IgE leader sequences in fusion proteins which comprise protein sequences derived from the same species and of genetic constructs which encode fusion proteins having IgE leader sequence linked to protein sequences derived from the same species were conceived by him and his co-inventors prior to the effective filing date of Levinson. In addition, the Declaration of David B. Weiner states that the conception of using IgE leader sequences in fusion proteins which comprise immunomodulatory protein sequences and of genetic constructs which encode fusion proteins having IgE leader sequence linked to immunomodulatory protein sequences were conceived by him and his co-inventors prior to the effective filing date of Levinson. The Declaration of David B. Weiner establishes that the disclosure of subject matter in Levinson regarding the use of the IgE leader sequence is the invention of the currently named inventors and that as disclosed in Levinson in the vaccines against IgE mediated allergy disclosed in Levinson the use of IgE leader was derived from the invention of the current inventors The relevant portion of Levinson is was derived from Applicants' own work and therefore not prior art under 35 U.S.C. 102(e) (see In re Mathews, 408 F.2d 1393, 161 USPQ 276 (CCPA 1969) and In re DeBaun, 687 F.2d 459, 214 USPQ 933 (CCPA 1982)).

For the foregoing reasons, Applicants respectfully request that the rejection of claims 1, 14, 16, 17, 19, 55, 56, 58-60, 66, 67, 69-71 and 77 under 35 U.S.C. 103(a) as being unpatentable over Yang et al. in view Letvin et al. and Levinson et al. and Meazza et al. be withdrawn.

Yang et al. in view Letvin et al., Levinson et al., Meazza et al. and further in view of Aarts et al.

Claims 1,15, 55, 57, 66, and 68 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Yang et al. in view Letvin et al., Levinson et al. and Meazza et al. as applied to claims 1, 14, 16, 17, 19, 55, 56, 58-60, 66, 67, 69-71 and 77 above, and further in view of Aarts et al. (Aarts et al., Vector-based vaccine/cytokine combination therapy to enhance induction of immune responses to a self-antigen and anti-tumor activity, *Cancer Res.* 62(20):5770-7, 2002).

As noted above, the disclosure in Levinson regarding the use of the IgE leader sequence is Applicants' invention and therefore, the cited teachings in Levinson used to establish the prima facie case are not available for such use.

For the foregoing reasons, Applicants respectfully request that the rejection of claims 1, 14, 16, 17, 19, 55, 56, 58-60, 66, 67, 69-71 and 77 under 35 U.S.C. 103(a) as being unpatentable over Yang et al. in view Letvin et al. and Levinson et al. and Meazza et al. and further in view of Aarts et al. be withdrawn.

Conclusion

Claims 1, 14-17, 19, 55-60, 66-71 and 77 are in condition for allowance. An executed version of the Declaration shall be forwarded to the USPTO forthwith. A notice of allowance is earnestly solicited. Applicants invite the Examiner to contact the undersigned at 610.640.7855 to clarify any unresolved issues raised by this response.

The Commissioner is hereby authorized to charge any deficiencies of fees and credit of any overpayments to Deposit Account No. 50-0436.

Respectfully submitted,
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Attachment: Unexecuted Declaration of David B. Weiner